

## **Remarks**

Applicant respectfully requests reconsideration and allowance of this application in view of the amendments above and the following comments. Applicant respectfully submits that the amendments are fairly based on the specification and respectfully request their entry.

Applicant respectfully points out that the claims have been amended above such that, there are now two independent claims (1 and 12) and new dependent claims 13, 14, 15, 16, 17, and 18 have been added to depend from new claim 12. Claim 11 has been cancelled.

Applicant's amendments to claim 1 and the introduction of new claim 12 are in response to the Examiner's suggestion at page 11, which conclude the numbered paragraph 10, of the Office Action mailed February 24, 2003. The Examiner suggested therein that two applications encompassed by original main claim 1 could be recited and claimed separately, to provide clarity and definiteness in claiming the invention. Therefore, Applicant has amended claim 1 such that it is now directed to the binding type assay discussed at pages 7-8 of the specification. New claim 12 has been inserted above and is directed to the chemical or enzymatic type assay discussed at pages 8-9 of the specification. New claims 13, 14, 15, 16, 17 and 18 correspond to the further limitations contained in original claims 3, 5, 6, 7, 8, and 9, respectively.

Applicant respectfully submits that the above amendments are in accordance with the Examiner's suggestions. Further, Applicant points out that in amending or drafting steps "a)" and "d)" of claims 1 and 12, Applicant has endeavored to employ more specific wording in accordance with the Examiner's suggestions. The amendments to the claims are discussed in further detail, in response to the rejections set forth below.

**35 U.S.C. § 112, SECOND PARAGRAPH REJECTION OF CLAIMS 1, 3, 5-9 & 11**

Claims 1, 3, 5-9 & 11 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Specifically, the Examiner objects to what is viewed as vague and confusing language and redundancies. Applicant respectfully traverses this rejection for the reasons set forth below.

Regarding the above rejection as applied to claim 1, step a), with respect to the phrase "said reagent being the same for all of said carrier beads and for all of said N populations" and its perceived meaning, Applicant points out that the phrase has been amended above. Applicant has amended claim 1, step a) to recite "said reactant being the same for said carrier beads in all of said N populations", in accordance with the Examiner's suggestion. Applicant points out that the term "reagent" previously employed has now been replaced in claim 1, with - - reactant - -, as supported in the specification, for example, at page 7, line 27 and page 10, line 15. Applicant believes use of the term "reactant" provides further distinction from the term "reagents", which appears at step "d)".

Regarding Applicant's use of the term "the same" with respect to the "reactant" Applicant respectfully submits that one of ordinary skill in the art would, in view of the specification, would appreciate that "same" means the same type or identity of reactant. Applicant submits that the amended language above, clarifies the meaning of step a) and therefore, step a) is now definite. Thus, Applicant respectfully requests that the above rejection with respect to claim 1, step a) be reconsidered and withdrawn.

Regarding the above rejection as applied to claim 1, step d), with respect to the recitation "providing in a fluid medium in each of said N different reaction vessels, additional reagents for performing an assay" and its perceived lack of clarity regarding the order of the steps, Applicant respectfully submits that the claim need not be limited to a particular order. Applicant points out that the carrier beads, samples and reagents may be added to the reaction vessel in an order that is practical or convenient. The order of addition, may be influenced by the particular application or analyte in question. Applicant should be permitted to broadly claim the instant method.

In response, to the Examiner's objections to the phrase "performing said assay" Applicant points out that claim 1, as amended above, no longer contains the objectionable phrase. Regarding Applicant's use of the term "the same" in referencing "reagents" Applicant, again respectfully submits that one of ordinary skill in the art would, in view of the specification, would appreciate that "same" means the same type or identity of reagent.

Regarding the above rejection as applied to claim 1, step d), with respect to the recitation “wherein one of said additional reagents or said reagent bound to the carrier beads, carries a signal moiety that is partitioned between said carrier beads and said fluid medium during the assay, in each of said N different vessels” and its perceived lack of clarity, Applicant respectfully points out that claim 1 as amended above, no longer contains this objectionable recitation.

However, Applicant respectfully draws the Examiner’s attention to new claim 12, which is directed to a chemical or enzymatic type assay, and points out that new claim 12 contains a similar recitation to that objected to by the Examiner. Therefore, Applicant respectfully requests that the Examiner reconsider the similar language as used in new claim 12. Applicant maintains that the specification provides ample guidance to one of ordinary skill in the art to recognize the relationships among terms such as: reagents, carrier beads, compound to be tested and samples.

Applicant submits that the amended language above, clarifies the meaning of claim 1, step d) and therefore, step d) is now definite. Thus, Applicant respectfully requests that the above rejection with respect to claim 1, step d) be reconsidered and withdrawn.

Regarding the above rejection as applied to claim 1, step f), parts i) and ii) and the perceived lack of clarity regarding how the signal moiety and the detectable label provide

the desired measures, Applicant respectfully submits that the claims are not analyzed in a vacuum, but always in light of the specification to which the claims are attached. In this case Applicant points out that the specification provides ample guidance to one of ordinary skill in the art to recognize the various structural and functional relationships between the assay components. Given the various possible binding, chemical or enzymatic reactions that may take place, as set forth in the specification, it would be apparent to one of ordinary skill, how the signal moiety and /or detectable label can provide the desired indications. Furthermore, claim 1, as amended above at step “d)”, provides further clarity on the binding reactions that take place within the claimed method. Applicant submits that step f) is clear when read in the context of the whole claim and specification.

Regarding the above rejection as applied to claim 6, with respect to the recitation “the reagent that is bound to said carrier bead, of the reagents recited in step d) is provided on said carrier beads, which are precoated with said reagent”, Applicant respectfully points out that claim 1 as amended above, no longer contains this objectionable recitation. Claim 6 now recites “wherein said reactant or reagent, bound to said carrier beads is pre-coated on said carrier beads”, in accordance with the Examiner’s suggestion. Thus, the basis for the above rejection as applied to claim 6 has been eliminated.

Regarding the above rejection as applied to claim 11, Applicant respectfully points out that claim 11 has been cancelled above. Thus, the basis for the above rejection

as applied to claim 11 has been eliminated. In view of the amendments and comments above, Applicant respectfully requests that the above rejections under 35 U.S.C. § 112, second paragraph, be reconsidered and withdrawn.

### **35 U.S.C. § 102(e) REJECTION OF CLAIM 11**

Claim 11 is rejected under 35, U.S.C. § 102(e) as anticipated by Chandler et al., US 5,981,180 (hereinafter “Chandler”) for reasons of record. Applicant respectfully traverses this rejection for the reasons set forth below.

In response to the above rejection Applicant respectfully points out that claim 11 has been cancelled. Thus, the basis for the above rejection of claim 11 has been eliminated. Therefore, Applicant respectfully requests that the rejection be withdrawn.

### **New Grounds of Rejection**

### **35 U.S.C. § 103(a) REJECTION OF CLAIMS 1, 3, 5-7 and 9**

Claims 1, 3, 5-7 and 9 are rejected under 35, U.S.C. § 103(a) as being unpatentable over Chandler et al., US 5,981,180 (hereinafter “Chandler”) in view of Yamashita et al., US 6,210,900 (hereinafter “Yamashita”). Specifically, in presenting the *prima facie* case of obviousness, the Examiner sets forth elements of the instant invention as claimed, conceding that Chandler fails to disclose the elements. The Examiner

continues by presenting the disclosure of Yamashita, which in Applicant's view, fails to supply teaching or motivation to combine the references and arrive at the claimed invention. The Examiner, however, then concludes that it would have been obvious to one of ordinary skill in the art at the time of the instant invention to combined the reaction samples of Chandler into a mixture and apply the analysis methods of Yamashita. Applicant respectfully traverses this rejection for the reasons set forth below.

In response to the above rejection, Applicant respectfully submits that the Examiner has not established a prima facie case of obviousness over the cited references. The thrust of the Examiner's rejection appears to be that the reaction samples of Chandler can be combined and analyzed by the methods of Yamashita. Applicant, first, points out that the "samples" of Chandler, containing multiple analytes in a single sample, are not the same as Applicant's multiple samples, "each containing a single compound to be tested." Furthermore, the Examiner concedes, at the bottom of page 7 of the Office Action that Chandler fails to disclose many elements of the claimed method, most notably "adding thereto one of N samples into each reaction vessel . . . ." The Examiner, continues by presenting the teachings of Yamashita and refers to column 4, lines 16-37 of Yamashita in an apparent effort to show that Yamashita supplies what Chandler lacks. In response, Applicant, next points out that the disclosure of Yamashita, at page 4, lines 16-37 shows the use of pre-encoded beads generated by a combinatorial labeling process as supports for combinatorial synthesis of compounds on the surface of the beads.

*is pre-encoded*

Clearly, Yamashita does not teach the use of a method with pre-existing compounds that are not coupled to beads. Consequently, Yamashita does not disclose the dispensing of “samples each containing a single compound to be tested” into reaction vessels, as instantly claimed. The method of Yamashita is not compatible with use of diverse libraries of compounds and/or compounds which are not compatible with attachment to beads. Additionally, the method is not suitable of use in analyses that are not compatible with an analyte attached to beads.

Restating, Chandler in combination with the Yamashita reference does not teach Applicant’s inventive method as claimed. Chandler lacks many of the features of Applicant’s invention, as set forth by the Examiner at page 7 of the Office Action. Yamashita does not teach the use of a method with pre-existing compounds that are not coupled to beads. Additionally, neither Chandler or Yamashita teaches the addition of multiple samples containing a single compound to be tested, as instantly claimed. These limitations are present in all of Applicant’s claims, either directly or by virtue of their dependence from claim 1 or 12.

In view of the above deficiencies of the cited references, Applicant respectfully submits that there is no motivation or suggestion to combine the disparate teachings of the Chandler and Yamashita references to arrive at Applicant’s claimed invention. Therefore, Applicant submits that the presently claimed invention is patentably nonobvious over the prior art. Thus, it is respectfully requested that the above rejection be reconsidered and withdrawn.



**35 U.S.C. § 103(a) REJECTION OF CLAIM 8**

Claim 8 is rejected under 35, U.S.C. § 103(a) as being unpatentable over Chandler et al., in view of Yamashita et al., and further in view of Mandecki, US 5,641,634 (hereinafter "Mandecki"). Specifically, the Examiner concedes that Chandler and Yamashita fail to disclose bead populations that are electronically labeled. The Examiner continues by presenting Mandecki, as teaching electronically encoded carrier beads. The Examiner then asserts that it would have been obvious to one of ordinary skill in the art at the time of the instant invention to electronically encode populations of beads as disclosed by Mandecki, in the method of Chandler as modified by Yamashita because, Mandecki discloses its applicability in multiplex assays. Concluding, the Examiner states that one of ordinary skill in the art would have been motivated to incorporate the teachings of Mandecki into the method of Chandler as modified by Yamashita and because, Mandecki disclosed the advantage thereof, in further detecting and differentiating increased numbers of analytes simultaneously in assays. Applicant respectfully traverses this rejection for the reasons set forth below.

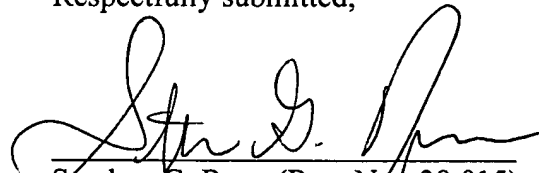
As discussed above, in connection with the rejection of claims 1, 3, 5-7 and 9 under 35 U.S.C. § 103(a), the Chandler and Yamashita references do not teach Applicant's inventive method as claimed. Chandler, fails to teach many of the elements of the claimed method. Yamashita does not teach the use of a method with pre-existing compounds that are not coupled to beads. Additionally, neither Chandler or Yamashita

teaches the addition of multiple samples containing a single compound to be tested as instantly claimed. These limitations are present in all of Applicant's claims, either directly or by virtue of their dependence from claim 1 or 12.

The above deficiencies of the Chandler and Yamashita references are not remedied by Mandecki. Mandecki does not provide any teachings regarding the addition of multiple samples containing a single compound to be tested. Consequently, the Examiner has not established a *prima facie* case of obviousness, with respect to the inventive method as claimed. In view of the above deficiencies of the cited references alone or in combination, the presently claimed invention is patentably nonobvious over the prior art. Thus, it is respectfully requested that the above rejection be withdrawn.

Early and favorable action is earnestly solicited.


Respectfully submitted,

  
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Signature: 

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